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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/326,020 | 06/04/1999 | JOHN ROBERT PORTER | CELL-0072 | 3600 |

7590

03/12/2003

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EXAMINER

ROBINSON, BINTA M

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 03/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/326,020

Applicant(s)

PORTER ET AL.

Examiner

Binta M. Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,5-12 and 14-19 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other:

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Detailed Action

The 112, second paragraph rejections of claims 1 and 14 are withdrawn in light of applicant's remarks and amendment at paper no. 35/D. The 112, first paragraph rejection of claims 18-19 are withdrawn in light of applicant's amendment at paper no. 35/D. The restriction requirement made at paper no. 19 is made FINAL.

(Old Rejections)

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 15 in part is rejected under 35 U.S.C. 112, first paragraph, for reasons of record at paper no. 33. The fifth Wands factor of the predictability in the art of these compounds on the various unrelated diseases, the sixth Wands factor of the amount of direction provided by the inventor in terms of the use of these compounds for the treatment of specific diseases, and seventh Wands factor of the provision of working examples of the use of these compounds in the treatment of specific diseases are not satisfied.

In terms of the breadth of the claims, a method of treating diseases involving inflammation in which the extravasations of leukocytes plays a role in

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a mammal is being claimed. Alk1 of the compound of formula (1a) also encompasses a broad breadth C1-6 heteroaliphatic chain containing one, two, and three or four heteroatoms or heteroatom-containing groups. The nature of the invention is that these compounds are useful in the treatment of disorders involving inflammation. In terms of the fifth and sixth Wands factor, the level of predictability in the art is low and the amount of direction provided by the inventor is low since the applicant does not specify the test results for each of the tests compounds. The applicant also does not test these compounds effects on actual specified diseases. In terms of the 8th Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application. Additionally, the eighth Wands factor of the quantity of experimentation needed to make or use the invention based on the content of the disclosure is not satisfied. Undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claims are enabled by the instant specification.

(modified rejection)

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

 Claims 1, 5-11 and 14-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for Alk1 in the compound of formula (Ia) equaling C1-6 heteroaliphatic chain containing one, two, three or four heteroatoms or heteroatom-containing groups selected from the claimed group nor does the specification enable the treatment of all diseases or disorders involving inflammation in which the extravasation of leukocytes plays a role in a mammal with these compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement. The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. The applicant is referred to *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in Ex parte Foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy

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the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In *re Wands*, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

In terms of the breadth of the claims, a method of treating diseases involving inflammation in which the extravasation of leukocytes plays a role in a mammal is being claimed. Alk1 of the compound of formula (1a) also encompasses a broad breadth C1-6 heteroaliphatic chain containing one, two, and three or four heteroatoms or heteroatom-containing groups. The nature of the invention is that these compounds are useful in the treatment of disorders involving inflammation. In terms of the fifth and sixth Wands factor, the level of predictability in the art is low and the amount of direction provided by the inventor is low since the applicant does not specify the test results for each of the tests compounds. The applicant also does not test these compounds effects on actual specified diseases. In terms of the 8th Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

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3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

✓ Claims 1, 12, and 14 in part are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claim 1, line 3, page 3 of the amendment 32/C, the phrase "salts, solvates, hydrates and N-oxides thereof." Is indefinite. The applicant is only claiming "A compound" which is one compound, yet this phrase implies that more than one more compound is being claimed. It is suggested that the phrase be amended to –salts, solvates, hydrates or N-oxides thereof."

✓ B. In claim 14, line 14, page 4 of the amendment 32/C, the phrase "salts, solvates, hydrates and N-oxides thereof." Is indefinite. The applicant is only claiming "A compound" which is one compound, yet this phrase implies that more than one more compound is being claimed. It is suggested that the phrase be amended to –salts, solvates, hydrates or N-oxides thereof."

✓ C. In claim 12, line 1, page 3 of the amendment 28/B, the phrase "salts, solvates, hydrates and N-oxides thereof." Is indefinite. The applicant is only claiming "A compound" which is one compound, yet this phrase implies that more than one more compound is being claimed. It is suggested that the phrase be amended to –salts, solvates, hydrates or N-oxides thereof."

Claim 13 is objected to because it is base on a rejected claim.

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Response to Applicant's Remarks**112, first paragraph rejection of claim 15**

The applicant alleges that the full scope of the subject matter defined by the claims is enabled without undue experimentation; the specification teaches one of ordinary skill in the art how to pharmaceutical compositions containing the claimed compounds and how to use these compositions. The applicant also alleges that the examiner has failed to provide any credible evidence as to why claim 15 is not enabled and that the examiner makes only conclusory statements and that the only statement made in support of the rejection in the April 26, 2001 office action was the there is no cure for multiple sclerosis. However, the examiner stated at office action no. 29, that the applicant has not enabled the treatment of the various diseases claimed, many of which are unrelated with the claimed compounds. The examiner also said at paper no. 29, that claim 15 did not satisfy the sixth, seventh, and eighth Wands factors.

Specifically, the level of predictability in the art is low and the amount of direction provided by the inventor is low since the applicant does not specify the test results for each of the tests compounds. The applicant also does not test these compounds effects on actual specified diseases.

Contrary to the applicant's assertion, the full scope of the claimed subject matter is not enabled. The applicant is claiming compounds as defined in claim 15 where alk1 in the compound of formula (1a) can be equaling C1-6 heteroaliphatic chain containing one, two, three or four heteroatoms or heteroatom-containing groups selected from the claimed group. The applicant

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is claiming a scope of rings yet to be discovered or synthesized. For example, 4 heteroatoms in one ring have not been made. The applicant has not enabled even a representative scope of the compounds that he is claiming.

The applicant also alleges that the examiner has failed to provide any explanation whatsoever as to why the specification is not enabling for the cited compounds of formula Ia regarding claims 1, 5-11 and 14-19. The applicant also asserts that the amendment made at paper no. 35/D obviates the rejection.

However, the examiner notes that the examiner has provided scientific reasons and relied on the Foreman factors of *In re Wands* and *Ex parte Foreman* as to why these compounds were not enabled. Specifically, the level of predictability in the art is low and the amount of direction provided by the inventor is low since the applicant does not specify the test results for each of the tests compounds. The applicant is claiming a scope of rings yet to be discovered or synthesized. For example, 4 heteroatoms in one ring have not been made. The applicant has not enabled even a representative scope of the compounds that he is claiming.

112, second paragraph rejection

The applicant traverses the 112, second paragraph rejection of the phrase "salts, solvates, hydrates and N-oxides thereof". The applicant alleges that one of ordinary skill in the art would recognize that this phrase implies that more than one compound is being claimed. However, the applicant cannot claim more than one compound in a claim that begins with the phrase "A compound" which claims only one compound. A "pharmaceutical composition" claim is the

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appropriate type of claim for claiming more than one compound, not a "compound" claim.

The IDS filed 6/9/00, 2/15/00, 2/10/00, 7/19/99, 12/17/99, 8/21/00, , 4/27/01, 7/11/01, have been considered.

The applicant also does not test Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5437. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers for the organization where this application or proceeding is

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assigned are (703)308-7922 for regular communications and (703)308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0193.

March 5, 2003



ALAN L. ROTMAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600